K071310

JUN - 8 2007

SECTION 9 — 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name: *syngo* CT Oncology - Software Package

Classification Name: Accessory to Computed Tomography System Classification

Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Wittelsbacherplatz 2
D-80333 Muenchen, Germany

4. Contact Person:

Dr. Kristin Frowein
Regulatory Submissions Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9638
Fax: +49 9191 18-9782

5. Date of Preparation of Summary: January 25, 2007

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Substantial Equivalence

The ***syngo* CT Oncology** software package that is addressed in this premarket notification, is substantially equivalent to the following commercially available software package:

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	LungCARE CT SW Package	K022013	07/16/2002
2. Edda Technology, Inc.	IQQA-Liver	K061696	11/13/2006
3. GE Medical Systems	Advantage Windows Tissue Volume Option	K963345	10/18/1996
4. Siemens AG	*syngo* Multimodality Workstation (feature: Image Fusion)	K010938	06/26/2001

8. Device Description and Intended Use:

syngo CT Oncology is a self-contained, non invasive image analysis software package designed to fast-track routine diagnostic oncology, staging and follow-up. Flexible layouts and automated image registration facilitate the synchronous display and navigation of multiple datasets for viewing multi-phase CT data and easy follow-up comparison. The application provides a range of automated tools specifically designed to support physicians in the segmentation and volumetric evaluation of suspicious lesions including dedicated tools for lung, liver and lymph node assessment in CT data. Dedicated workflow-support and integrated, accumulative reporting allow to track lesions and their changes in e.g. size, shape and enhancement pattern over time. *syngo* CT Oncology also facilitates functional imaging offering fusion with other modalities such as PET data. It also features *syngo* LungCAD for detecting small lung nodules (PMA-approved).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Siemens AG Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8 N.W., Suite 104
NEW BRIGHTON MN 55112-1891

JUN - 8 2007

Re: K071310
Trade/Device Name: *syngo* CT Oncology – Software Package
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 22, 2007
Received: May 25, 2007

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3 INDICATION FOR USE

510(k) Number (if known): K071310

Device Name: *syngo* CT Oncology - Software Package

Indications for Use:

syngo CT Oncology is a self-contained, non invasive image analysis software package designed to support the physician in routine diagnostic oncology, staging and follow-up. Flexible layouts and automated image registration facilitate the synchronous display and navigation of multiple datasets for viewing multi-phase CT data and easy follow-up comparison. The application provides a range of interactive tools specifically designed for segmentation and volumetric analysis of lesions and includes dedicated tools to support the physician in lung, liver and lymph node assessment in CT data. Dedicated workflow-support and integrated, accumulative reporting help to track lesions and their changes in e.g. size, shape and enhancement pattern over time. *syngo* CT Oncology also facilitates functional imaging offering fusion with other modalities such as PET data. It also features *syngo* LungCAD for detecting small lung nodules (PMA-approved).

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071310